

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

IN RE: VALSARTAN, LOSARTAN, AND
IRBESARTAN PRODUCTS LIABILITY
LITIGATION

No. 1:19-md-2875-RBK
Hon. Robert Kugler

**PLAINTIFFS' RESPONSE TO WHOLESALER DEFENDANTS' OBJECTION
IN PART TO SPECIAL MASTER REPORT AND ORDER NO. 46**

Plaintiffs, by and through the Plaintiffs' Executive Committee, respectfully file this response to Wholesaler Defendants' Objection in Part to the Special Master Report and Order No. 46 (ECF 1695).

I. Introduction

Wholesaler Defendants only object to two aspects of the Special Master's Report and Order No. 46: (i) class plaintiffs' standing to assert claims on behalf of absent class members, and (ii) the assertion of certain claims under states' consumer protection statutes. Wholesaler Defendants' objection as to standing is partially redundant of Manufacturer Defendants' objection on the same point. Therefore, for efficiency's sake, Plaintiffs adopt here in full its separate response to Manufacturer Defendants' objection.

Wholesaler Defendants additionally base their objection to the standing ruling as to the so-called traceability element of Article III standing (the Manufacturer and Retail Pharmacy Defendants did not object to this aspect of the Special Master's standing ruling). The Court should overrule this objection. This Court's MTD Order No. 2 granted Plaintiffs leave to amend the master complaints to clarify if any named plaintiffs in the Economic Loss and Medical Monitoring

Master Complaints purchased valsartan that had been distributed by one or more Wholesaler Defendants. As this Court rightly recognized, this was not a high hurdle. Plaintiffs only had to amend to allege that, “for each named defendant, at least one named plaintiff must be able to allege an injury to that defendant.” MTD Order No. 2 (ECF 728) at 17.

Plaintiffs did this in their amendments. The Special Master correctly acknowledged this and, consistent with Supreme Court and Third Circuit precedent, as well as this Court’s prior MTD ruling, granted Plaintiffs leave to amend the Economic Loss and Medical Monitoring Master Complaints to allege certain claims against Wholesaler Defendants.¹

Wholesaler Defendants’ objection simply rehashes the same arguments they made before this Court on the motion to dismiss briefing, and again before the Special Master on the motion for leave to amend briefing. Their objection does not cite any new law, let alone an intervening change in controlling law. Defendants do not get a third bite at the apple. The Special Master’s ruling is consonant with Supreme Court and Third Circuit law, as well as this Court’s own law of the case, and therefore should not be disturbed.

Wholesaler Defendants’ objection as to claims under states’ consumer protection statutes should be overruled as well. This Court’s MTD Order No. 4 dismissed without prejudice “state consumer protection statute claims that sound in fraud.” ECF 818 at 29. The Special Master followed this, and only granted Plaintiffs leave to amend the master complaints to assert claims under consumer protection statutes that do not require a showing of fraud. ECF 1614 at 29. The Master Complaints filed on November 1, 2021 abide by this, insofar as they only allege a subset

¹ Article III standing was just the threshold inquiry. The Special Master disallowed many claims against Wholesaler Defendants. Plaintiffs abided by this and, in their amended Master Complaints filed on November 1, 2021, only alleged the few claims that the Special Master allowed to proceed against Wholesaler Defendants.

of states’ consumer protection statutes that do *not* require a showing of fraud. Thus, Wholesaler Defendants’ belated argument (without any citation to legal authority) that such amendment would be “futile” is inconsistent with this Court’s prior ruling, the Special Master’s well-reasoned ruling, and existing caselaw. Wholesaler Defendants’ objection should be overruled.

II. Background

For brevity, for purposes of these pleadings only and without any waiver of any rights, and because Wholesaler Defendants did not include any background section in their own objection, Plaintiffs generally accept Manufacturer Defendants’ recitation of the background and procedural history pertinent to the matter currently before the Court. *See* ECF 1690-1 at 4-9.

III. Standard of Review

Federal Rule of Civil Procedure 53 permits the Court to appoint a Special Master “to address pretrial and posttrial matters.” Fed. R. Civ. P. 53(a)(1)(C). The Court’s appointment order of December 22, 2020 (ECF 692) in this matter authorizes the Special Master to “oversee the schedule for completion of discovery and all discovery disputes and motions....The authority of the Special Master hereunder shall be coextensive with that of a United States Magistrate Judge.” *See* 12/22/20 Order (ECF 692). While an abuse of discretion generally applies to procedural or non-dispositive issues decided by a special master, *Valeant Pharms. Int’l Inc. v. AIG Ins. Co. of Canada*, No. 18-493, 2020 WL 7768405, at *4 (D.N.J. Dec. 30, 2020), a court should review de novo all objections to conclusions of law or findings of fact. *In re Johnson & Johnson Derivative Litig.*, Nos. 10-233, 11-4993, 11-2511, 2013 WL 6163858, at *3 (D.N.J. Nov. 25, 2013).

IV. Argument

A. The Special Master's Standing Ruling Should Not Be Disturbed

1. The Special Master Report and Order No. 46 Accurately Addressed Named Plaintiffs' Standing to Represent Absent Class Members in Other States Whose Laws Present a "False Conflict"

Because Wholesaler Defendants' objection completely overlaps with Manufacturer Defendants' objection on this point, Plaintiffs incorporate by reference their response to Manufacturer Defendants' objection.

2. Traceability

This Court's MTD Order No. 2 granted Plaintiffs leave to amend the master complaints to clarify if any named plaintiffs in the Economic Loss and Medical Monitoring Master Complaints purchased valsartan that had been distributed by one or more Wholesaler Defendants. At that time, Wholesaler Defendants argued that each and every named plaintiff and absent class member had to track precisely which valsartan product they bought which had been distributed by which Wholesaler Defendant. This Court disagreed, rightly recognizing that the traceability aspect of Article III standing was not a high hurdle. This Court ruled that Plaintiffs only had to amend to allege that, "for each named defendant, at least one named plaintiff must be able to allege an injury to that defendant." MTD Order No. 2 (ECF 728) at 17. Wholesaler Defendants never sought reconsideration of this ruling.

Plaintiffs then addressed this in their amendments. On the motion for leave to amend briefing, Wholesaler Defendants once again re-raised their faulty, unduly-exacting traceability argument. The Special Master rebuffed that argument, just as this Court had earlier done, stating:

The Wholesaler Defendants argue that there are named Plaintiffs in the PELMC and the PMMMC that do not trace their purchases of VCDs to each Wholesaler Defendant. But the standard is not whether each named Plaintiff has traced her injuries to each Defendant. Instead, the test is whether *a* named Plaintiff has traced

her injury to *a* particular Defendant. The PELMC and the PMMMC satisfy this standard for the Wholesaler Defendants. (*See* PELMC, ECF No. 1382-4, ¶¶ 153, 156, and 159; PMMMC, ECF No. 1382-6, ¶¶ 501, 503, 505.)

ECF 1614 at 7-8.

a. Wholesaler Defendants Do Not Cite Any New Law or Intervening Change in Controlling Law

Wholesaler Defendants' objection does not cite any new law that they did not cite in their motion to dismiss briefing or motion for leave to amend briefing, law overlooked by this Court or the Special Master, or an intervening change in controlling law. Wholesaler Defendants' objection should be overruled on this basis alone.

b. Class Plaintiffs Adequately Plead Traceable Injuries

Because Wholesaler Defendants simply rehash their same arguments again for a third time, Plaintiffs set forth below their argument presented to the Special Master as well.

For Plaintiffs to show traceability, an "indirect causal relationship will suffice." *Pitt News v. Fisher*, 215 F.3d 354, 360 (3d Cir. 2000). This standard is less than the proximate causation needed to succeed on the merits of a tort claim. *See Pub. Interest Research Group of N.J., Inc. v. Powell Duffryn Terminals Inc.*, 913 F.2d 64, 72 (3d Cir. 1990). Article III does not require Plaintiffs to plead precisely who among plausible tortfeasor Defendants caused each and every one of their injuries, and to suggest otherwise would "raise the standing hurdle higher than the necessary showing for success on the merits." *Friends of the Earth, Inc. v. Laidlaw Envir. Servs. (TOC), Inc.*, 528 U.S. 167, 181 (2000). This is especially true in complex pharmaceutical cases involving multiple actors in the drug supply chain such as manufacturers, distributors, wholesalers, and pharmacies. Notwithstanding the above, Plaintiffs *have* supplied detailed allegations regarding i) the business practices of the Defendants which allows for product tracing, and ii) each Defendant that was involved at every level of the supply chain that resulted in a specific Plaintiff purchasing

a VCD.

Taking the allegations of the Economic Loss and Medical Monitoring Master Complaints as true, Plaintiffs' injuries more than exceed the baseline standard necessary to show sufficiently plead traceability. Amended allegations describe, in painstaking detail, the granular level of data each Defendant maintains (and must maintain, as a matter of law) that permit product identification and tracing. *See* PELMC ¶¶ 170-196; PMMMC ¶¶ 144-163. For instance, each drug sold in the United States is encoded with "a unique 10-digit code (the National Drug Code, or NDC) that follows the product from manufacturing through retail dispensing." *See* PELMC ¶¶ 197-200; PMMMC ¶¶ 164-166. "The NDC is a critical component of each and every transfer of a prescription drug (from the manufacturer to the wholesaler; from the wholesaler to the retailer; and from the retailer to the consumer) and therefore every transaction is accompanied by and labeled with the NDC." PELMC ¶¶ 177-179; PMMMC ¶¶ 144-146. "This same code is used by TPPs in the real-time claims adjudication process to identify the precise dollar amount they will reimburse the pharmacy for a particular prescription drug purchase." PELMC ¶¶ 177-179. Each Manufacturer Defendant's VCDs were coded with a unique NDC number, which allows for the identification and tracing of their product from manufacturer through the distribution chain to final dispensing to consumers. PELMC ¶¶ 177-179; PMMMC ¶¶ 144-146.

Were this not enough, "[i]n many cases, the 'Lot' number will also appear on the prescription bottle provided to the consumer and, thus, specifically indicate information including whether a recall applies to the particular pills in the bottle" PELMC ¶ 179; PMMMC ¶ 146. "The Lot number is also used to report issues arising around a particular drug. For example, lot numbers are used by pharmacists to report Adverse Events ('AE') (patient-specific side effects or complications associated with the use of a prescription drug)." PELMC ¶ 180; PMMMC ¶ 146.

“A key part of the DSCSA [Drug Supply Chain Security Act] is the requirement that “product tracing information should be exchanged” for each transaction and retained for at least six years, including the following transaction information (“TI”):

- Proprietary or established name or names of the product
- Strength and dosage form of the product
- National Drug Code (NDC) number of the product
- Container size
- Number of containers
- Lot number of the product
- Date of the transaction
- Date of the shipment, if more than 24 hours after the date of the transaction
- Business name and address of the person from whom and to whom ownership is being transferred

PELMC ¶ 193; PMMMC ¶ 160.

The DSCSA adds an additional layer of identification and mandates the “use of a composite ‘product identifier’ that Manufacturer Defendants were required to begin applying to prescription drug packages and cases.” PELMC ¶ 194; PMMMC ¶ 161. This is reflected in Defendants’ own ordinary-course operations. For example, “[p]ublicly available Guidelines published by Defendant AmerisourceBergen require that ‘each Prescription Drug lowest saleable unit’ it receives from a manufacturer must have the clearly indicated product identifier on the unit label. In addition, case labels, and partial case labels must list the lot number and expiration date.”

PELMC ¶¶ 195-196; PMMMC ¶¶ 162-163.

The PELMC and PMMMC explain how the above sources of information kept in the ordinary course of business allow each Plaintiff or absent class member to identify who manufactured, distributed, or sold each VCD they purchased. In addition, for each named Plaintiff, the PELMC and PMMMC expressly allege the *specific* Manufacturer, Wholesaler, and Retail Pharmacy Defendant who made, distributed, or dispensed that Plaintiff’s VCDs. For instance, the PELMC alleges for Plaintiff Borkowski:

Plaintiff Alphonse Borkowski is a New York resident and citizen. During the class period Plaintiff Borkowski paid money for one or more of Defendants' VCDs, including purchases of VCDs manufactured, distributed, or sold by one or more ZHP Defendants (as defined *infra* Part II.C). This product ("ZHP Product") bore a unique NDC which denoted that it was indeed sold, manufactured, or distributed into the United States drug supply chain by the ZHP Defendants. Specifically, the ZHP Product that Plaintiff Borkowski purchased was manufactured by Defendant ZHP, and sold in the United States by Defendant Solco with the assistance of Defendant Huahai US and Defendant Princeton, who facilitated the regulatory approval of the ZHP product necessary for sale. At least some of this ZHP Product ultimately purchased by Plaintiff Borkowski was purchased from Defendant ZHP by Defendant McKesson who then distributed and resold that ZHP Product to Defendant Rite Aid (among other Retail Pharmacy Defendants). Defendant Rite Aid, in turn, sold the ZHP Product to Plaintiff Borkowski and other consumers. Each Defendant mentioned in this paragraph expressly and impliedly warranted to Plaintiff Borkowski (either directly, or indirectly by adopting warranties that were passed along to and incorporated by another Defendant further downstream and mentioned in this paragraph) that their respective generic VCDs were the same as their RLDs. But in fact, Plaintiff Borkowski purchased a product that was not the same to the RLD. Had Plaintiff Borkowski known the product was not the same as the RLD, Plaintiff Borkowski would not have paid for these Defendants' VCDs. Likewise, had these Defendants' deception about the impurities within their products been made known earlier, Plaintiff Borkowski would not have paid for these Defendants' VCDs.

PELMC ¶ 15. This allegation identifies who made the VCDs (ZHP), who distributed the VCDs (McKesson), and specifically who dispensed the VCDs (Rite Aid) to Mr. Borkowski. The PELMC and MMMC provide this detail for the other named consumer Plaintiffs. PELMC ¶¶ 14-58; PMMMC ¶¶ 396-412. The allegations also follow this pattern for TPP Plaintiffs by including illustrative data for their insureds and the VCDs for which TPP Plaintiffs reimbursed. *See* PELMC ¶¶ 59-72.

Unable to refute the factual reality that a wealth of product information and tracing data is maintained as part of the pharmaceutical industry's business operations, Manufacturer Defendants resort to arguing that because *each and every* VCD purchase by Plaintiffs is not traceable to *each and every* Defendant these claims are somehow not traceable at all. *See* Manuf. Opp'n to Amendment at 11-13. Wholesaler Defendants and Retail Pharmacy Defendants further argue that

each named Plaintiff must identify and trace, now at the pleadings stage, the exact product purchased at each and every sale over many years. *See* Wholesaler Opp’n Amendment at 5-13; Retail Pharmacy Opp’n to Amendment at 25-26, 32-33. These arguments lack merit. The Court’s order was clear: “in order to establish standing in the class action context, for each named defendant, *at least one* named plaintiff must be able to allege *an* injury traceable to that defendant.” MTD Order No. 2 at 17 (emphasis added). The Economic Loss and Medical Monitoring Master Complaints do this, and much more, thereby addressing the deficiencies outlined in MTD Opinion 2.

The Wholesaler Defendants argue that to meet the Article III standing requirement of traceability, each named Plaintiff must identify the exact product they purchased that any Wholesaler Defendant distributed.² This is neither the standard, nor consistent with the Court’s earlier ruling. *See* MTD Order No. 2 at 16-17. At the pleading stage, an indirect causal connection is sufficient to establish standing as long as there is “a fairly traceable connection between the alleged injury in fact and the alleged conduct of the defendant.” *Vt. Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 771 (2000). “In the context of a class action, Article III must be satisfied by at least one named plaintiff.” *Neale v. Volvo Cars of N. Am.*, 794 F.3d 353, 359 (3d Cir. 2015) (internal quotation omitted). Here, at least one named Medical Monitoring Plaintiff and at least one Economic Loss Plaintiff has tied their claims to each Wholesaler Defendant. That is enough.

Wholesaler Defendants assert that Plaintiffs must establish that *each* named Plaintiff has an injury traceable to *each* Wholesaler Defendant. *See* Wholesaler Br. at 6-7. Their argument is

² It is ironic that the Wholesaler Defendants are arguing that their own inadequate product tracing should be a credible basis for frustrating the Plaintiffs’ claims.

based on two points: first, that because some class representatives may not identify a specific wholesaler, they lack standing as to those wholesalers; and second, that Plaintiffs fail to meet the traceability requirement because they do not identify the exact unit of contaminated valsartan distributed by each Wholesaler. Neither point withstands scrutiny.

There are the numerous named Plaintiffs who trace their injuries to one or more of Wholesaler Defendants.³ For example, PMMMC Plaintiffs Judson and Daring, between the two of them, identify all three Wholesaler Defendants, and they by themselves satisfy class-wide Article III standing. *See* PMMMC at ¶¶ 397, 402, 500, 502-504.

That some new proposed named plaintiffs have yet to elicit facts to identify specific Wholesaler Defendants (*see* Wholesaler Opp'n to Amendment at 5) is irrelevant to the question of whether the complaints sufficiently trace some injury to each Wholesaler Defendant. Moreover, the facts necessary to plead with this specificity were only revealed in Defense Fact Sheets, which have yet to be completed for newly proposed named plaintiffs. In essence, Wholesaler Defendants seek to dismiss claims on the basis that Plaintiffs have not adequately plead cognizable claims – when the information necessary to achieve the heightened pleading standard articulated by the Wholesaler Defendants is squarely within their own control. This reality alone demonstrates the futility of the Wholesaler Defendants' argument. That discovery revealed facts necessary for the many existing named plaintiffs identified above substantiates the prior allegations and temporary use of the "John Doe Wholesaler" allegations for new named plaintiffs.

³ For instance, Plaintiffs Borkowski, Cacaccio, Semmel, Kaplan, Lee, Longwell, Mullins, Neal, Nelson, Wineinger, Judson, Zehr, and Kruk allege they purchased VCDs that were distributed by McKesson. PELMC ¶ 155; PMMMC ¶ 502. Plaintiffs Bruner, Duffy, Erwin, Mullins, Powell, Judson and Roberts allege they purchased VCDs that were distributed by AmerisourceBergen. PELMC ¶ 158; PMMMC ¶ 504. And Plaintiffs Gildner, Mullins, Daring, Silberman and Nelson allege they purchased VCDs that were distributed by Cardinal Health. PELMC ¶ 152; PMMMC ¶ 500.

Plaintiffs have plead that they purchased and/or consumed VCDs bearing the same NDC code as that distributed by each Wholesaler Defendant. Plaintiffs reviewed pharmacy records and the Defendant Fact Sheets provided by Wholesaler Defendants and have confirmed that each Wholesaler Defendant was responsible for distributing the batch of contaminated valsartan ultimately consumed by at least one named Plaintiff. PELMC ¶¶ 144-159; PMMMC ¶¶ 397-412. The Wholesaler Defendants' only dispute is that not *every* named Plaintiff identified the exact contaminated VCD unit that each Wholesaler Defendant distributed. This argument sidesteps the reality that the Plaintiffs' allegations at this stage need not establish proof of proximate causation. *See Powell Duffryn*, 913 F.2d at 72. Moreover, Plaintiffs' allegations as to common NDC codes, taken as true at this stage, make a sufficient showing that the contaminated VCDs they consumed can be fairly traced⁴ to each Wholesaler Defendant.

B. The Special Master's Ruling on Consumer Protection Statute Claims Should Not Be Disturbed

Wholesaler Defendants' objection as to claims under certain states' consumer protection statutes should be summarily overruled. For one, their terse argument cites no error of law, no error of fact, no new case law, no intervening change in controlling law, and, in fact, no caselaw whatsoever. ECF 1695-1 at 17-18. This is reason enough to overrule their objection.

Second, Wholesaler Defendants' motion for leave to amend briefing never took on the matter of consumer protection statutes that require a showing of fraud versus those which do not. They simply argued then that, to the extent a given state's consumer protection statute sounds in fraud, those claims should be disallowed along with the common-law fraud claims. *See*

⁴ In their Motion, Defendants primarily rely on *Franklin*, but that case is distinguishable. In *Franklin*, the plaintiffs were unable to trace their injury from each of their 100 different mutual funds to the advisor and director defendants. 388 F. Supp. 2d at 456. Here, Plaintiffs' amended allegations link the unique NDC codes to each Wholesaler with at least one named Plaintiff.

Wholesaler Opp'n to Amendment at 33. As Wholesaler Defendants never raised before the Special Master any argument that claims under state consumer protection statutes that do *not* sound in fraud should *also* be disallowed, they waived this argument and cannot raise it for the first time with this Court. *See, e.g., In re NCAA Student Loan Trust*, 971 F.3d at 444 (“Arguments not presented to a magistrate judge and raised for the first time in objections to the magistrate's recommendations are deemed waived.”); *Washington v. Gilmore*, No. 17-988, 2021 WL 688088, at *2 (W.D. Pa. Feb. 23, 2021) (collecting cases) (“Issues raised for the first time in objections to the magistrate judge’s recommendation are deemed waived.”).

In any event, this Court’s MTD Order No. 4 dismissed without prejudice “state consumer protection statute claims that sound in fraud.” ECF 818 at 29. The Special Master’s ruling followed this Court’s ruling, and only granted Plaintiffs leave to amend the master complaints to assert claims under consumer protection statutes that do not require a showing of fraud. ECF 1614 at 29. The Master Complaints do this, and specify only a subset of states’ consumer protection statutes that do not require a showing of fraud.

V. Conclusion

The parties extensively briefed Plaintiffs’ motion for leave to amend the master complaints. Defendants filed more than 200 pages of opposition briefs and sur-replies. The Special Master thoughtfully evaluated all of the briefing and the applicable law. On the issue of standing, he correctly granted Plaintiffs leave to amend the Master Economic Loss and Master Medical Monitoring Complaints consistent with Supreme Court and Third Circuit law. Those amended Master Economic Loss and Amended Medical Monitoring Complaints were filed on November 1, 2021. Manufacturer Defendants present no valid reasons to disturb the Special Master’s Report and Order No. 46. Accordingly, Wholesaler Defendants’ objection in part to the Special Master’s

Report and Order No. 46 should be overruled.

Dated: November 24, 2021

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 24th day of November, 2021, I caused a true and correct copy of the foregoing to be filed and served upon all counsel of record by operation of the Court's CM/ECF system.

/s/ David J. Stanoch

David J. Stanoch